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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/596,545 VINK ET AL. Office Action Summary Examiner Art Unit MELANIE YU 1641 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 30 December 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-5.7 and 9-16 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-5,7 and 9-16 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 16 June 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date ______.

5) Notice of Informal Patent Application

6) Other:

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DETAILED ACTION

Applicant's amendment filed 30 December 2008 has been entered.

Status of the Claims

Claims 1-5, 7 and 9-16 are pending in this application. Claims 6, 8 and 17-21 are canceled.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 1, 3-5, 12, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (US 2003/0087311) in view of Potyrailo et al. (US 6,538,725).
 Wolf teaches a device comprising:

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a first fluorescent label of fluorescein, which has optical properties (conjugate element of FRET is the label, par. 6 and 38; dyes have optical properties, par. 38; fluorescein, par. 68 and 69) and provided with at least one binding site that is able to selectively bind a molecule (FRET conjugate attached to analyte binding ligand and has binding site specific for analyte-analogue, par. 6) and when bound to the binding site, quenches the luminescence of the first fluorescent label (binding incurs a quenching of donor fluorescence, par. 63 and 122); and

a photodetector for detecting the optical properties of the label when the molecule selectively binds to the surface and for outputting a signal in response to the signal of the nanowire that indicates whether the molecule is bound to the binding site and is quenching the signal of the nanowire (fluorometer, par. 6, 121 and 122). Wolf fails to teach the label being a nanowire.

Potyrailo et al. teach a luminescent nanowire or a fluorescent dye used as a luminescent label (col. 6, lines 50-60), in order to provide labels that have high long-term stability.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the fluorescein label in the device of Wolf, a nanowire label as taught by Potyrailo et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected labeling effect would have been obtained. The use of alternative and functionally equivalent techniques would

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have been desirable to those of ordinary skill in the art based on the economics and availability of components.

With respect to claim 3, Wolf teaches the molecule being a biomolecule (analyteanalogue is a biomolecule, par. 43, 44 and 95).

Regarding claims 4 and 5, Wolf teaches a biomolecule (analyte-analogue is the biomolecule, par. 43, 44 and 95) labeled with a dye (analyte-analogue includes either donor or acceptor label and analyte binding ligand contains either the donor or acceptor molecule, par. 22) having an absorption spectrum (acceptor emits light at a second wavelength, par. 58) which overlaps in frequency with a spectrum (par. 59) of the first fluorescent label (luminescence nanowire and the conjugate FRET label, which may be a nanowire according to Potyrailo et al.).

With respect to claim 12, Wolf teaches the dye label suspended in a fluid in the sensor (par. 124) and when combined with Potyrailo et al., the nanowire label would be suspended in the fluid.

Regarding claim 13, while the prior art does not disclose drop depositing the suspension of nanowires on a substrate, such a limitation is merely an intended use which the prior art would inherently be capable of doing. The only distinction between applicant's claims and the prior art is recited in the functional language. It is incumbent upon applicant to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USPQ 563 @ 566 (CCPA 1971) and *In re Swinehartetal*. 169 USPQ 226 @ 229 (CCPA 1971).

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With respect to claim 16, Wolf in view of Potyrailo et al. teach the device being a nanowire sensor (Potyrailo, col. 6, lines 50-60) for the detection of an analyte, wherein the at least one binding site is able to selectively bind an analyte, wherein the optical properties of the labels are used for analyte detection (Wolf, par. 6).

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being obvious over Wolf (US 2003/0087311) in view of Potyrailo et al. (US 6,538,725), as applied to claim 1, further in view of Laing (US 2003/0096275) and Vo-Dinh et al. (WO 00/43552, published 27 July 2000, the corresponding US patent 6,743,581 is relied upon for citations).

Wolf in view of Potyrailo et al. teach a fluorometer detector, but fail to teach the detector comprising a substrate including a phototransistor and an optical filter on the phototransistor, wherein the nanowire is disposed on the optical filter.

Laing teaches a fluorescence spectrophotometer, which is a fluorometer, or a phototransistor detector (par. 123 and 132), in order to provide fluorescence detection.

Vo-Dinh et al. teach a substrate including a phototransistor detector (integrated photodetector system, Fig. 1A, col. 38, lines 35-38; col. 6, line 49-col. 7, line 9), an optical filter disposed on the phototransistor (emission filter, Fig. 1A, col. 8, lines 18-22) and the substance to be detected disposed on the optical filter (sampling platform, Fig. 1A; col. 8, lines 7-9) passing light having a wavelength corresponding to a detection spectrum and reflecting light at other wavelengths (col. 8, lines 18-22), in order to filter out the signal to be detected.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Wolf in view of Potyrailo et al., a

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phototransistor detector as taught by Laing. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detector and since only the same fluorescence signal would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include on the phototransistor detector in the device of Wolf in view of Potyrailo et al. further in view of Liang, an optical filter having a substance to be detected disposed on the optical filter as taught by Vo-Dinh et al., in order to obtain a more accurate signal detection.

 Claims 7, 9, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (US 2003/0087311) in view of Potyrailo et al. (US 6,538,725), as applied to claim 1, further in view of Empedocles et al. (US 2004/0005723).

Wolf in view of Potyrailo et al. teach nanowires doped with pigments, metals and semiconductors (Potyrailo, col. 6, lines 50-60), but fail to specifically teach the nanowire comprising an activator ion.

Empedocles et al. teach a nanowire doped to comprise an activator ion (par. 116-117) and growing the nanowires onto a surface (par. 29) and the nanowires in an array (par. 7), in order to provide an assay array for detection of an analyte in a sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the nanowires of Wolf in view of Potyrailo et al.,

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grown on a substrate, formed in an array pattern and doped to comprise an activator ion as taught by Empedocles et al., in order to provide nanowires that are individually distinguishable (par. 121 and 127) and are releasable from the substrate (par. 27).

With respect to claim 11, Wolf in view of Potyrailo et al. teach a plurality of different fluorescent labels to detect different analyte (par. 38) and Potyrailo et al. teach a fluorescent label being a nanowire, but the prior art references fail to teach at least two nanowires having different sizes.

Empedocles et al. teach at least two nanowires having different sizes (par. 18 and 127), in order to provide nanowires that produce different signals (par. 121).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in Wolf in view of Potyrailo et al. in light of Kale et al., nanowires having different sizes as taught by Empedocles et al., in order to provide nanowires with different fluorescent signals to detect multiple analyte in a sample.

 Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (US 2003/0087311) in view of Potyrailo et al. (US 6,538,725), as applied to claim 1, further in view of Lieber et al. (US 2002/0117659).

Wolf in view of Potyrailo et al. teach a first nanowire modified with at least one first binding site (Wolf, par. 6), but fail to teach a second nanowire modified with a second binding molecule different from the first nanowire and the nanowire grown onto a porous matrix.

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Lieber et al. teach a device comprising a first nanowire modified with a first binding site and a second nanowire modified with a second binding site, wherein the molecules of the first and second binding molecules are different from each other (par. 164), in order to provide detection of multiple analyte in a single sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in addition to the first nanowire having a first binding site in the device of Wolf in view of Potyrailo et al., a second nanowire modified with a second binding site with different binding molecules on the first and second nanowires to detect different analyte as taught by Lieber et al., in order to detect multiple analytes in a sample.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (US 2003/0087311) in view of Potyrailo et al. (US 6,538,725), as applied to claim 1, in view of Empedocles et al. (US 2004/0005723), as applied to claim 14, further in view of Lieber et al. (US 2002/0117659).

Wolf in view of Potyrailo et al. further in view of Empedocles et al. teach a nanowire grown onto a surface, but fail to teach the nanowire grown into a porous matrix.

Lieber et al. teach a nanowire grown onto a substrate (par. 121) or into a porous matrix (par. 92), in order to provide elongated nanowires that are functionalized for detection of analyte in a sample..

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the substrate of Wolf in view of Potyrailo et

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al. further in view of Empedocles, a porous matrix as taught by Lieber et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent substrate and since the same expected grown nanowire effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Response to Arguments

- Applicant's arguments with respect to the rejection of the claims under 35 USC
 102(e) over Lieber et al. have been fully considered and are persuasive. The previous rejections over this reference have been withdrawn.
- Applicant's arguments filed 30 December 2008 regarding the rejection under 103(a) over Wolf in view of Potyrailo et al. have been fully considered but they are not persuasive..

Applicant argues that the prior art references fail to teach a binding site that is able to selectively bind a molecule that when bound to the binding site, quenches the luminescence of the nanowire, and a photodetector provided for detecting the luminescence of the nanowire and outputs a signal in response to the luminescence of the nanowire that indicates whether the molecule is bound to the binding site and is quenching the luminescence of the nanowire. Applicant's argument is not persuasive because Wolf teaches an assay having a label with a binding site that selectively binds a molecule (analyte-analogue) that, when bound to the binding site, quenches the luminescence of the first label and outputs a signal that is detected by a photodetector.

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Wolf only fails to teach the first label being a nanowire. This deficiency is cured by the prior art reference of Potyrailo et al., which teach that a fluorescent label may be a nanowire, as described above. Therefore, the prior art reads on the claims rejected under 103(a) over Wolf in view of Potyrailo et al..

- 10. Applicant's arguments with respect to the rejection(s) of claim(s) 2, 7, 9, 10 and 14-16 under 35 USC 102(e) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the teachings of Wolf, Potyrailo et al. and Vo-Dinh et al..
- 11. Regarding the objection to the specification, the objection has been withdrawn in view of applicant's arguments.

Conclusion

- No claims are allowed.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/ Patent Examiner, Art Unit 1641